

**PATIENT INFORMATION LEAFLET: INFORMATION FOR THE
USER**

Isoniazid Tablets BP 100 mg*

Isoniazid

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any side effect gets serious, or if you notice any side effects not listed in this leaflet, please tell the doctor, health care provider or pharmacist

In this leaflet:

1. What Isoniazid Tablets BP 100 mg is and what it is used for
2. Before you take Isoniazid Tablets BP 100 mg
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4. Possible side effects
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1. WHAT ISONIAZID TABLETS BP 100 mg IS AND WHAT IT IS USED FOR

Isoniazid Tablets BP 100 mg is used for treating tuberculosis.

2. BEFORE YOU TAKE ISONIAZID TABLETS BP

100 mg Do not take Isoniazid Tablets BP 100 mg

- if you are allergic (hypersensitive) to isoniazid or any of the other ingredients of Isoniazid Tablets BP 100 mg (see section 6, What Isoniazid Tablets BP 100 mg contains)
- if you have acute liver disease
- if you liver disease which was caused by drugs

- if you have had liver damage before when taking isoniazid
- if you have had severe side effects with isoniazid, such as fever, chills or swelling of the joints.

Take special care with Isoniazid Tablets BP 100 Mg

You should tell your doctor or health care provider if you have any signs or symptoms of liver damage. These include: unexplained lack of appetite, nausea, vomiting, dark urine, yellowing of the skin and eyes (jaundice), rash, tingling in the hands and feet, persistent tiredness, weakness lasting longer than 3 days or abdominal tenderness, especially in the right upper region of your belly. Your doctor or health care provider will test your blood regularly to check for any problems with your liver.

You may be at special risk for developing hepatitis, if

- you are older than 35 years,
- if you drink alcoholic beverages daily (see “Taking Isoniazid Tablets BP 100 mg with food and drink”)
- if you have a chronic liver disease,
- if you are a user of injection drugs (e.g. heroin).

If you are at higher risk of developing hepatitis your doctor or health care provider will closely check your liver function.

Furthermore, you will be carefully monitored, if:

- you are taking any long-term medicines (see “Taking other medicines”),
- you feel numb or weak in your arms or legs or have prickling and tingling sensation on the skin (peripheral neuropathy),
- you are pregnant
- you have HIV infection.

Peripheral neuropathy (tingling in the hands and feet or feeling numb or weak in the arms or legs) is the most common side effect of isoniazid (see “Possible side effects”). If you have kidney problems, you may be at increased risk of isoniazid side effects.

Vitamin B₆, also called pyridoxine, can be given during treatment with Isoniazid Tablets BP 100 mg, because it largely reduces the risk of developing neuropathy.

If you are allergic (hypersensitive) to ethionamide, pyrazinamide, niacin (nicotinic acid),

or other related medications you may also be allergic to Isoniazid Tablets BP 100 mg.

You should tell your doctor or health care provider if you have diabetes or if you have ever suffered from seizure disorders (fits), psychosis, or liver problems.

It is important that your doctor or health care provider knows about all your symptoms even when you think they are not related to tuberculosis infection.

Taking other medicines

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of Isoniazid Tablets BP 100 mg, or Isoniazid Tablets BP 100 mg may affect their action. Side effects of either medicine may become worse or the medicines may become less effective.

You should not take Isoniazid Tablets BP 100 mg with disulfiram (medicine used for the treatment of alcoholism).

You should Isoniazid Tablets BP 100 mg at least one hour before taking medicines that contain aluminium hydroxide (used to treat indigestion).

The active agent in Isoniazid Tablets BP 100 mg may also interact with the following medicines:

- medicines to treat epileptic seizures (e.g. phenytoin, carbamazepine, valproic acid, phenobarbital)
- medicines used to help you sleep (benzodiazepines, e.g. diazepam, flurazepam, triazolam, midazolam)
- medicines for the treatment of certain psychiatric conditions (e.g. chlorpromazine, haloperidol),
- medicines for prevention of blood clots (coumarin or indandione derivatives, e.g. warfarin, phenindione)
- medicines used in surgery (opioids, e.g. alfentanil; anaesthetic e.g. enflurane)
- theophylline (medicine for asthma)
- procainamide (medicine for cardiac arrhythmias)
- corticosteroids (e.g. prednisolone, medicines for the treatment of inflammation and for

diseases such as asthma and rheumatoid arthritis),

- paracetamol (painkiller),
- medicines harmful to the liver,
- medicines harmful to the nervous system.

Taking Isoniazid Tablets BP 100 mg with food and drink

Isoniazid Tablets BP 100 mg should be taken on an empty stomach (at least one hour before a meal or two hours after a meal).

If you take cheese or fish while being treated with Isoniazid Tablets BP 100 mg, you may experience redness or itching of the skin, hot feeling, rapid or pounding heartbeat, sweating, chills or clammy feeling, headache, or lightheadedness.

Do not drink alcohol while taking Isoniazid Tablets BP 100 mg. This increases your risk for liver damage.

Pregnancy and breast-feeding

If you become pregnant, or are planning to become pregnant, you must contact your doctor or health care provider to discuss the potential benefits and risks of your tuberculosis therapy for you and your baby.

Isoniazid is present in breast milk. No harmful effects have been reported in breast-fed infants, whose mothers were taking isoniazid. However, the amount of isoniazid in breast milk is too low to protect your breast-fed baby against tuberculosis.

Driving and using machines

Isoniazid Tablets BP 100 mg may cause dizziness and other side effects to the nervous system that can reduce your ability to drive and use machines.

3. HOW TO TAKE ISONIAZID TABLETS BP 100 mg

Always take Isoniazid Tablets BP 100 mg exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

The dose of Isoniazid Tablets BP 100 mg was decided by your doctor or health care provider based on your body weight.

Active tuberculosis

Daily therapy

Adults:

In adults weighing 30–45 kg the daily dose is two Isoniazid Tablets BP 100 mg (200 mg) once daily.

In patients weighing over 45 kg the daily dose is three Isoniazid Tablets BP 100 mg (300 mg) once daily.

Children:

Number of Isoniazid Tablets BP 100 mg tablets by weight band to be taken once daily

Child's body weight	Number of Isoniazid Tablets BP 100 mg
3.5 kg to 7 kg	½ tablet once daily
7 kg to 10 kg	1 tablet once daily
10 kg to 15 kg	1½ tablets once daily
15 kg to 20 kg	2 tablets once daily
20 kg to 30 kg	2½ tablets once daily

Children weighing less than 3.5 kg should not take Isoniazid Tablets BP 100 mg, as appropriate dose adjustments cannot be made.

Latent tuberculosis

Adults:

The daily dose is three Isoniazid Tablets BP 100 mg (300 mg) as a single dose for at least 6 months.

Children:

Number of Isoniazid Tablets BP 100 mg by weight band to be taken once daily

Child's body weight	Number of Isoniazid Tablets BP 100 mg
Under 5 kg	½ tablet once daily
5.1–9.9 kg	1 tablet once daily
10–13.9 kg	1½ tablets once daily
14–19.9 kg	2 tablets once daily
20–24.9 kg	2½ tablets once daily
Over 25 kg	3 tablets once daily

Swallow Isoniazid Tablets BP 100 mg with water or another drink.

The tablets should be taken on an empty stomach (at least one hour before a meal or two hours after a meal).

If you take more Isoniazid Tablets BP 100 mg than you should

If you have taken too many tablets or if someone accidentally swallows some, you may develop nausea, vomiting, lack of appetite, gastrointestinal disturbances, fever, headache, dizziness, slurred speech, hallucinations and visual disturbances. Marked isoniazid overdoses can cause breathing problems and reduce consciousness progressing from stupor to coma, along with severe seizures. Immediately contact your doctor, health care provider or the nearest hospital emergency department for further advice.

If you forget to take Isoniazid Tablets BP 100 mg

If you miss or forget to take a dose, take the missed dose as soon as possible, unless the next regular dose is scheduled within 6 hours.

Skip the missed dose if it is almost time for your next regular dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Isoniazid Tablets BP 100 mg

Keep taking the medicine for as long as your doctor has told you, even if you are feeling better. If you stop the medicine too soon, your infection may not be completely cured.

You should not stop treatment unless your doctor or health care provider tells you to.

If you have any questions on the use of this product, ask your doctor or health care provider or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Isoniazid Tablets BP 100 mg can cause side effects, but not everybody gets them. When treating tuberculosis, it is not always possible to differentiate between unwanted effects caused by Isoniazid Tablets BP 100 mg or those caused by any other medicines you may be taking at the same time.

For this reason, it is important that you tell your doctor or health care provider of any change in your health.

The following side effects have been reported in patients treated with isoniazid.

The most important adverse effects of isoniazid is nerve damage (see below) and severe and sometimes fatal inflammation of the liver (hepatitis).

The *most commonly* reported side effects (greater than 1 in every 10 patients treated) are sensations of tingling, pricking, or numbness of the skin, especially in the feet and hands (peripheral neuropathy). Also, increases of liver enzymes as measured in blood samples. Usually, the levels of these enzymes return to normal within three months while you continue treatment. If the enzyme levels are too high, your doctor or health care provider may decide to stop treatment with Isoniazid Tablets BP 100 mg.

Uncommon side effects (greater than 1 in every 1000 patients treated) are inflammation of the liver (hepatitis), epileptic seizures, inflammation of the brain, personality changes and memory impairment. If you notice sign and symptoms suggestive of liver damage, tell your doctor or health care provider immediately (see “Take special care with Isoniazid Tablets BP 100 mg”).

The following side effects have been reported in patients treated with isoniazid. However, it is not known how frequently they occur:

- allergic reactions, including skin reactions, such as rash (exanthema, erythema) and itching (pruritus), but also severe forms with fever, blisters and involvement of the mucous membranes (e.g. erythema multiforme, Stevens-Johnson syndrome) inflammation of blood vessels (vasculitis), swollen or painful lymph nodes (lymphadenopathy), painful disorder affecting joints, muscles and other soft tissues (rheumatic syndrome, lupus-like syndrome) or life-threatening anaphylactic reactions,
- dizziness, headache, overresponsive reflexes, tremor, vertigo
- confusion, disorientation, hallucination
- inflammation of the lungs (pneumonitis)

- build-up of acid in the body (metabolic acidosis), increased blood levels of glucose, a vitamin deficiency syndrome called pellagra (with e.g. dementia, loose stools and skin inflammation)
- nausea, vomiting, loss of appetite, dry mouth, flatulence, constipation, abdominal pain
- difficulty in passing urine, kidney damage including kidney inflammation (interstitial nephritis)
- changes in the white blood cell counts (leucopenia, neutropenia, eosinophilia, agranulocytosis), possibly resulting in an increased risk of infection
- decreased red blood cell counts (anaemia), possibly leading to fatigue, weakness and shortness of breath
- decreased platelet count, possibly resulting in an increased risk of bruising and bleeding
- inflammation of the joints (arthritis)
- visual changes due to inflammation of the optic nerve (optic atrophy or neuritis)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist as soon as possible.

5. HOW TO STORE ISONIAZID ISONIAZID TABLETS BP 100 mg

Keep out of the reach and sight of children.

Do not store above 30°C. Keep in a well-closed container, protected from light.

Do not use Isoniazid Tablets BP 100 mg after the expiry date which is stated on the label, carton, bottle after expiry date. The expiry date refers to the last day of that month.

Medicines should not be disposed of in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Isoniazid Isoniazid Tablets BP 100 mg contains

The active ingredient is isoniazid.

The other ingredients are colloidal anhydrous silica, maize starch, microcrystalline cellulose, sodium edetate and stearic acid.

What Isoniazid Tablets BP 100 mg looks like and contents of the pack

White to off-white, flat, circular, bevelled-edge, uncoated tablets with break-line on one surface side and plain on other side.

The tablet can be divided into equal halves.

Blister packs: 10 tablets are packed in PVC/PVDC blister with aluminium seal, such 10 blisters are packed in a paper carton.

Supplier

Lupin Limited
Kalpataru Inspire
3rd Floor, Off Western Express Highway
Santacruz (East)
Mumbai 400055
India
Tel : + 91 22 66402372

Manufacturer

Lupin Limited
A-28/1, MIDC Industrial area
Chikalthana
Aurangabad 431 210
India
Tel: + 91 240 6612444
Fax: + 91 240 2484121